



OPERATING INSTRUCTIONS



B-Care₅ • Operating instructions

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Indications for Use

The B-Care₅ is intended for use as a component part of or optional accessory to the Stöckert S5 System (or any compatible system using the S5 firmware versions of 3.0 or greater), during cardiopulmonary bypass for procedures up to six hours. B-Care₅ is used exclusively for determining oxygen saturation, hematocrit value and temperature in the venous blood circuit.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.



Valid for the indicated firmware versions and higher:

Firmware release for ...	Release	(Internal designation)
System software	R3	(enblock_sys #y: R3.35)
All display and control modules	R3	(panel_display #y: R3.8)
B-Care ₅ sensor module	R3	(sensors_bloodgas #y: R3.x)

x: Indicates consecutive release number

y: Indicates consecutive device number

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1 B-Care₅ for the S₅/C₅ System

1.1 Terminology and abbreviations

► S ₅ System	Stöckert S ₅ System, modular heart-lung machine (in this case: overall system)
► C ₅ System	Sorin C ₅ System, compact heart-lung machine (in this case: overall system)
► B-Care ₅	Sorin System component of S ₅ /C ₅ System for determining the oxygen saturation, haematocrit value and blood temperature in the venous blood circuit. May only be operated with the S ₅ /C ₅ System.
► Sat %	Venous oxygen saturation (in %)
► v SAT O ₂	
► Hct %	Venous haematocrit value (in %)
► HCT	
► l/min (LPM)	Liters per minute

1.2 Safety

1.2.1 Approvals

B-Care₅ for the S₅/C₅ System has been designed to meet the following standards and regulations:

 0123	– Declaration of Conformity
IEC 60601-1	– Medical Electrical Equipment: General Requirements for Safety
IEC 60601-1-2	– EMC (electromagnetic compatibility)
MDD	– Medical Device Directive 93/42 EEC
DIN EN ISO 13485	– Quality Management System
UVV	– Regulations for Accident Prevention

B-Care₅ for the S₅/C₅ System is a medical device, class IIb (MDD 93/42). A Declaration of Conformity has been issued for B-Care₅.

1.2.2 Regulations and safety instructions

Usage in accordance with regulations

- ▶ B-Care₅ is intended for use as a component part of the S5/C5 System during cardiopulmonary bypass procedures up to six hours. B-Care₅ **is used exclusively for determining the oxygen saturation, haematocrit value and temperature in the venous blood circuit.** Any use beyond this specification is not in accordance with the regulations. SORIN GROUP DEUTSCHLAND GMBH will not assume any liability for damage in such a case. Use in accordance with regulations includes compliance with the operating instructions, as well as routine maintenance as outlined in the operating instructions.
- ▶ The relevant Regulations for Accident Prevention according to existing local regulations and employees' health and safety regulations must be complied with. SORIN GROUP DEUTSCHLAND GMBH will not accept any liability for damage due to non-compliance with these regulations.
- ▶ SORIN GROUP DEUTSCHLAND GMBH will not assume any liability for injuries and/or damage caused by failure to observe the safety and operating instructions or by the operator not taking due care. This also applies if the operator's duty to take due care has not been specifically expressed to the user.



General safety instructions

- ▶ B-Care₅ has been designed using state-of-the-art technology while adhering to accepted safety standards. Nevertheless, the patient, the user or other equipment may be put at risk during operation.
- ▶ B-Care₅ may only be used if in perfect working order and according to regulations and operating instructions. Be sure to take note of any cautions or warnings.
- ▶ The operating instructions for B-Care₅ should be kept close to the device at all times. Incomplete or illegible operating instructions must be replaced immediately.
- ▶ Also applicable to B-Care₅ in combination with the S5/C5 System (overall system): According to the European Directive 93/42 EEC and the national standards based on this directive, B-Care₅ must be subjected to a **regular maintenance check** by an authorized service technician. B-Care₅ must be subjected to this maintenance check every **1000 operating hours or every 12 months**, depending on which comes first.
- ▶ In addition to the operating instructions, the relevant legal, general and binding regulations concerning the prevention of accidents must be observed.
- ▶ In order to take situations into account which are clinic-specific and outside of normal routine, e.g. certain working procedures, the operating instructions must be supplemented with relevant instructions (supervision and registration requirements, etc.).
- ▶ An S5/C5 System is required to operate B-Care₅. You will find the firmware information inside the front cover and in the separate operating instructions for the S5/C5 System. Only authorized service technicians may upgrade the relevant firmware.
- ▶ If modifications affecting safety or performance come to notice when the overall system is not in use, do not use the machine and have it checked by an authorized service technician immediately.
- ▶ Do not modify or extend the system unless the changes have been tested and approved by SORIN GROUP DEUTSCHLAND GMBH. SORIN GROUP DEUTSCHLAND GMBH cannot assume liability or responsibility for unauthorized modifications or changes.

See "Usage in accordance with regulations" on page 1.2.

Safety instructions during operation

- ▶ B-Care₅ should only be operated and maintained by trained and qualified personnel.
- ▶ B-Care₅ must be monitored at all times during operation. Non-compliance with the responsibility of monitoring the equipment can put the patient at risk! The safety features of the overall system (alarm signals etc.) are intended to support the operator and do not free him from his responsibility to monitor the equipment continuously and conscientiously. 
- ▶ Medical conclusions must not be drawn from and interventions in the perfusion must not be carried out on the basis of B-Care₅ displays. Medical intervention and therapeutical procedure must not be based solely on the displays. 
- ▶ B-Care₅ does not offer absolute accuracy. Values determined by and displayed on B-Care₅ are trends and must be checked for plausibility.
- ▶ Position the measuring head correctly on the tube or on the reference element. Incorrect positioning can result in incorrect values.

Operational safety

- ▶ The safety guidelines for the overall system in which B-Care₅ is operated also apply to B-Care₅.
- ▶ The operator must read these operating instructions carefully and be familiar with the functionality before operating B-Care₅ for the first time!
- ▶ B-Care₅ may only be used with a S5/C5 System. Only one B-Care₅ may be used.
- ▶ The sensor module of B-Care₅ and the venous sensor constitute a unit and they should only be operated together.
- ▶ The operator should read the separate operating instructions for the S5/C5 System and be familiar with the functionality of the overall system before using B-Care₅ for the first time!
- ▶ Only authorized service technicians may upgrade B-Care₅. The sensor module and the measuring head constitute a unit and may not be operated separately. The measuring head values are stored in the sensor module.
- ▶ Alterations to the module or the use of spare parts and accessories which have not been tested and approved by SORIN GROUP DEUTSCHLAND GMBH could have a detrimental effect on the safety and operation of the overall system. In such cases, SORIN GROUP DEUTSCHLAND GMBH cannot accept any liability or responsibility.
- ▶ You should only use SORIN GROUP venous measuring connectors with a 1/2" or 3/8" diameter.
- ▶ The different measuring locations should be taken into account when the measured values of B-Care₅ and other measuring systems are compared.
- ▶ Values (e.g. blood flow, temperature, etc.) can fluctuate at the beginning and towards the end of a cardiopulmonary bypass procedure. This can lead to considerable deviation between the parameters displayed and the reference values of the laboratory device.

Safety instructions for routine maintenance

- ▶ Routine maintenance work should only be carried out by qualified personnel.
- ▶ The regulations concerning routine maintenance for the S₅/C₅ System in which B-Care₅ is used also apply to B-Care₅.
- ▶ Disconnect the overall system from the mains power supply before carrying out routine maintenance.
- ▶ You must always follow the regulations concerning routine maintenance outlined in these operating instructions.
- ▶ Always use recommended cleaning agents.
- ▶ Repairs should only be carried out by authorized service technicians. To guarantee safe and reliable operation of the module, only original spare parts from **SORIN GROUP DEUTSCHLAND GMBH** should be used.



1.3 General Information

For further information on

- ▶ system descriptions,
- ▶ installing and connecting sensor modules and sensors,
- ▶ basic operation,
- ▶ error and alarm displays,
- ▶ routine maintenance, and
- ▶ technical specifications for the overall system

please refer to the separate operating instructions for the S₅/C₅ System.

1.3.1 Scope of delivery

B-Care₅ for the S₅/C₅ System includes the following components:

- ▶ sensor module for B-Care₅
- ▶ venous sensor with measuring head (optical sensor and integrated thermister)
- ▶ holder for measuring head (reference element)
- ▶ operating instructions

An S₅/C₅ System (firmware version specified inside the front cover) is required to operate B-Care₅.

1.4 Operating B-Care₅ (venous)

1.4.1 Key icons and displays in the B-Care₅ (venous) menu

All of the touchscreen illustrations shown here are provided as examples only.

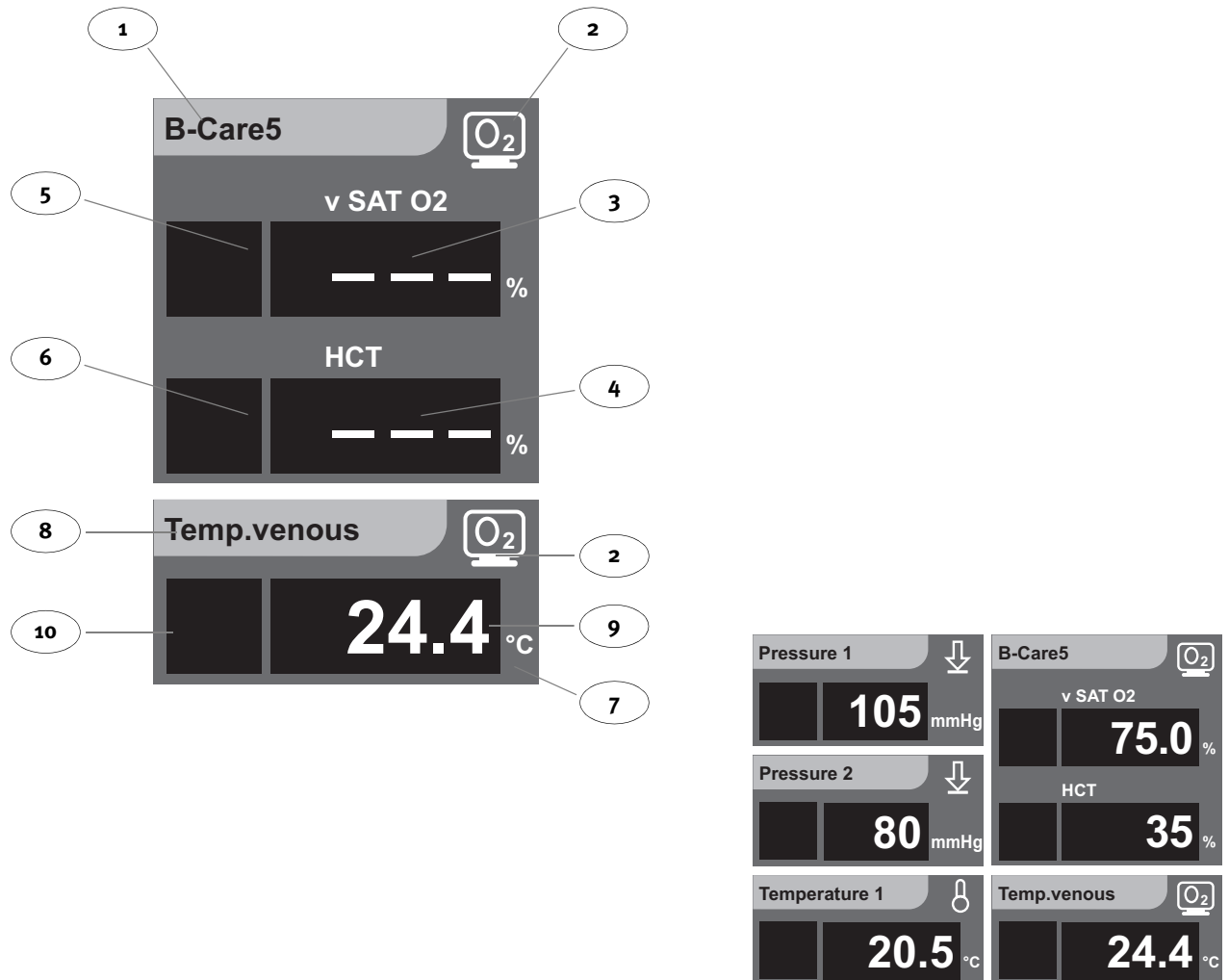


Fig. 1: B-Care₅ displet (with sample configuration on the S₅/C₅ System panel)

B-Care ₅	Item Name	Function	For information on entering the menu name, please refer to the separate operating instructions for the S ₅ /C ₅ System
	1 B-Care ₅ menu icon	Displays the name of the selected menu. Opens the entry displet of the functional group for entering parameters.	
	2 B-Care ₅ menu icon (venous)		
	3 v SAT O ₂ display	Oxygen saturation display (actual value in %)	
	4 HCT display	Haematocrit value display (actual value in %)	



- 5 Status display
v SAT O₂
and

Display during B-Care₅ self-test:
– self-test is not yet complete

- 6 status display HCT



Display:
– self-test is complete
– no adjustment has been carried out yet
(unadjusted status when switched on)



Display:
– the values for the laboratory adjustment have been stored, the adjustment with the laboratory values has not been carried out yet



Alarm display lights up red:
Alarm display when the set alarm limit or measurement range have been exceeded. An alarm tone also sounds simultaneously.



Warning display lights up yellow:
The measured values have exceeded the set warning limit values.
A warning tone sounds when the "Warning tone: On" option has been selected. (A warning tone does not sound when the "Warning tone: Off" option has been selected).

- 7 Displet for B-Care₅
venous temperature

Optional

- 8 Icon for B-Care₅
temperature menu

- 9 Display for B-Care₅
venous temperature

Displays the measured temperature (in °C)

- 10 Status display for
B-Care₅ venous
temperature

Only the key icons that can be activated in the displayed menu are shown (e.g. the key icon *Start/Stop*).

Note regarding temperature monitor:

The displays for the temperature monitor in combination with B-Care₅ are optional.

1.4.2 B-Care₅ menu (venous)

B-Care₅ (venous) menu (short: menu) can be opened using the displet.

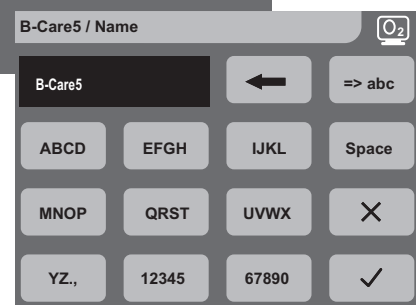
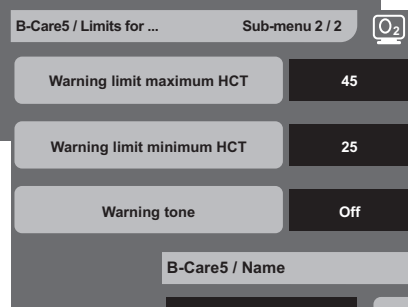
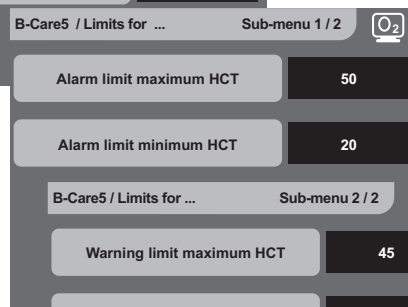
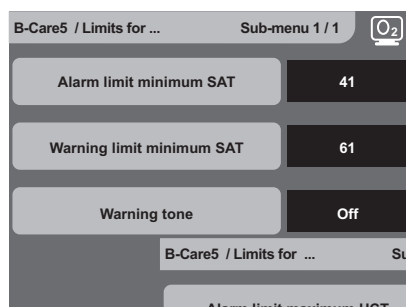
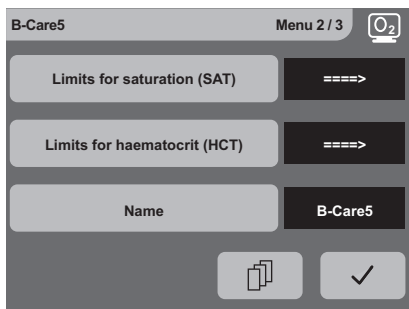
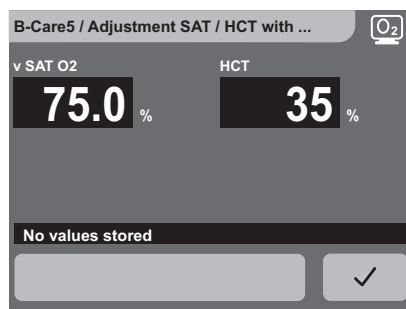
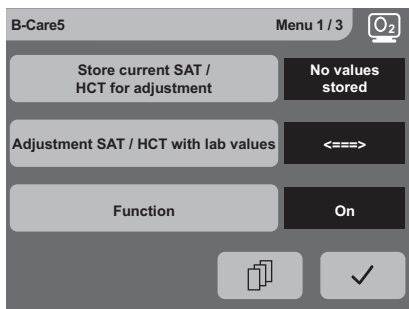
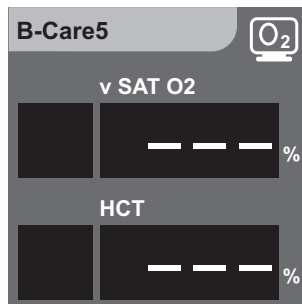


Fig. 2: Menu (1/2)

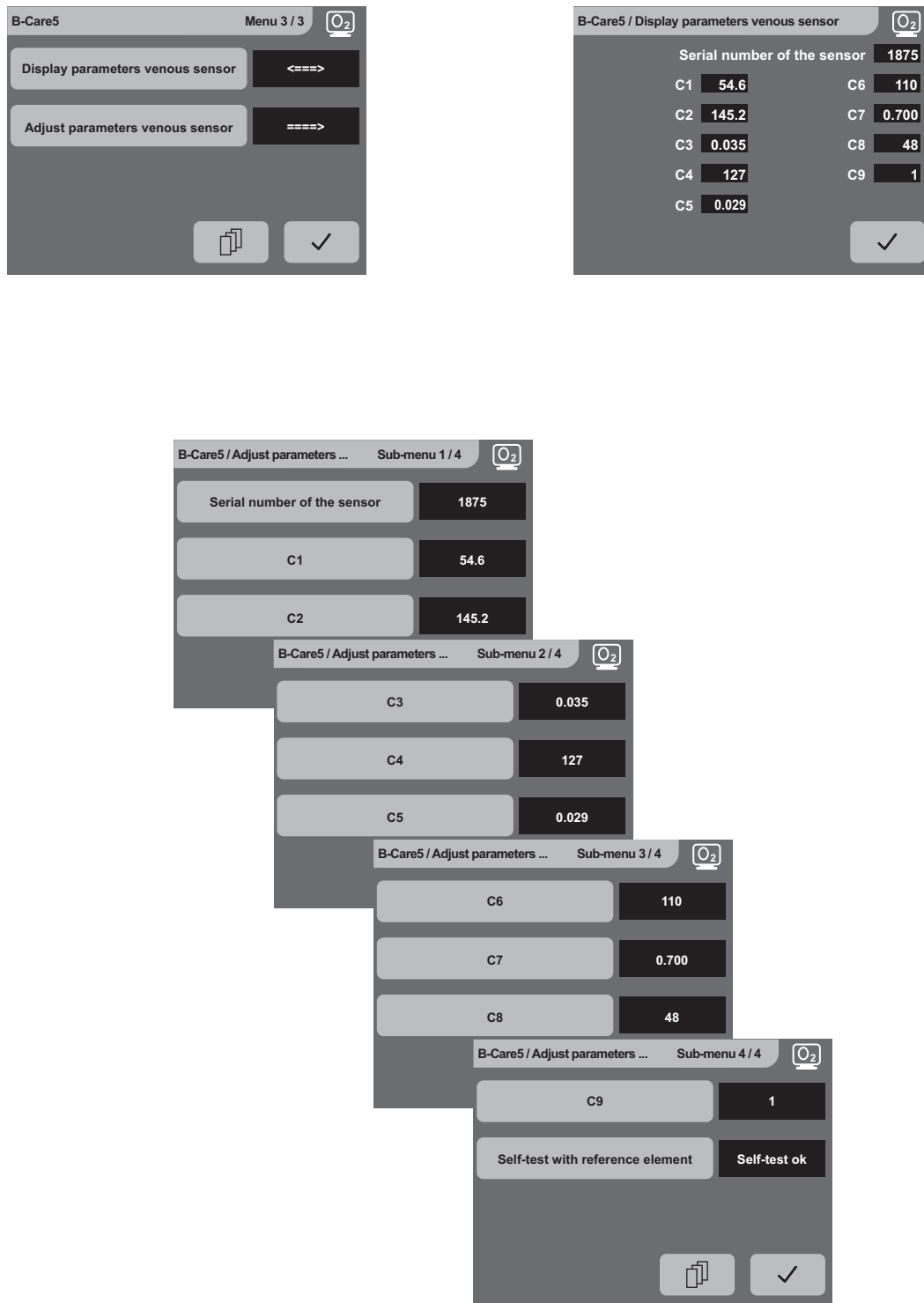


Fig. 3: Menu (2/2)

The optional temperature monitor allows the blood temperature in the venous blood circuit to be recorded. The assignment of the limit values and the operation is the same for all temperature channels. For more detailed information on operating the temperature monitor, please refer to the separate operating instructions for the S₅/C₅ System.

Configuring the B-Care₅ (venous)

Note: Please note that the sequence of entry displets shown in the operating instructions does not necessarily correspond to the sequence used in the S₅/C₅ System menus.

You should read the S₅/C₅ Systems' operating instructions carefully to ensure you are familiar with that system's functions before operating B-Care₅ for the first time.

Information on the procedure for entering and selecting numbers and letters can be found in the separate operating instructions for the S₅/C₅ System.

Warning: The parameters of B-Care₅ last set before switching off remain stored in the overall system.



Before switching on

The holder for the measuring head can be mounted at any height on the mast. The ideal position depends on how the overall system is set up:

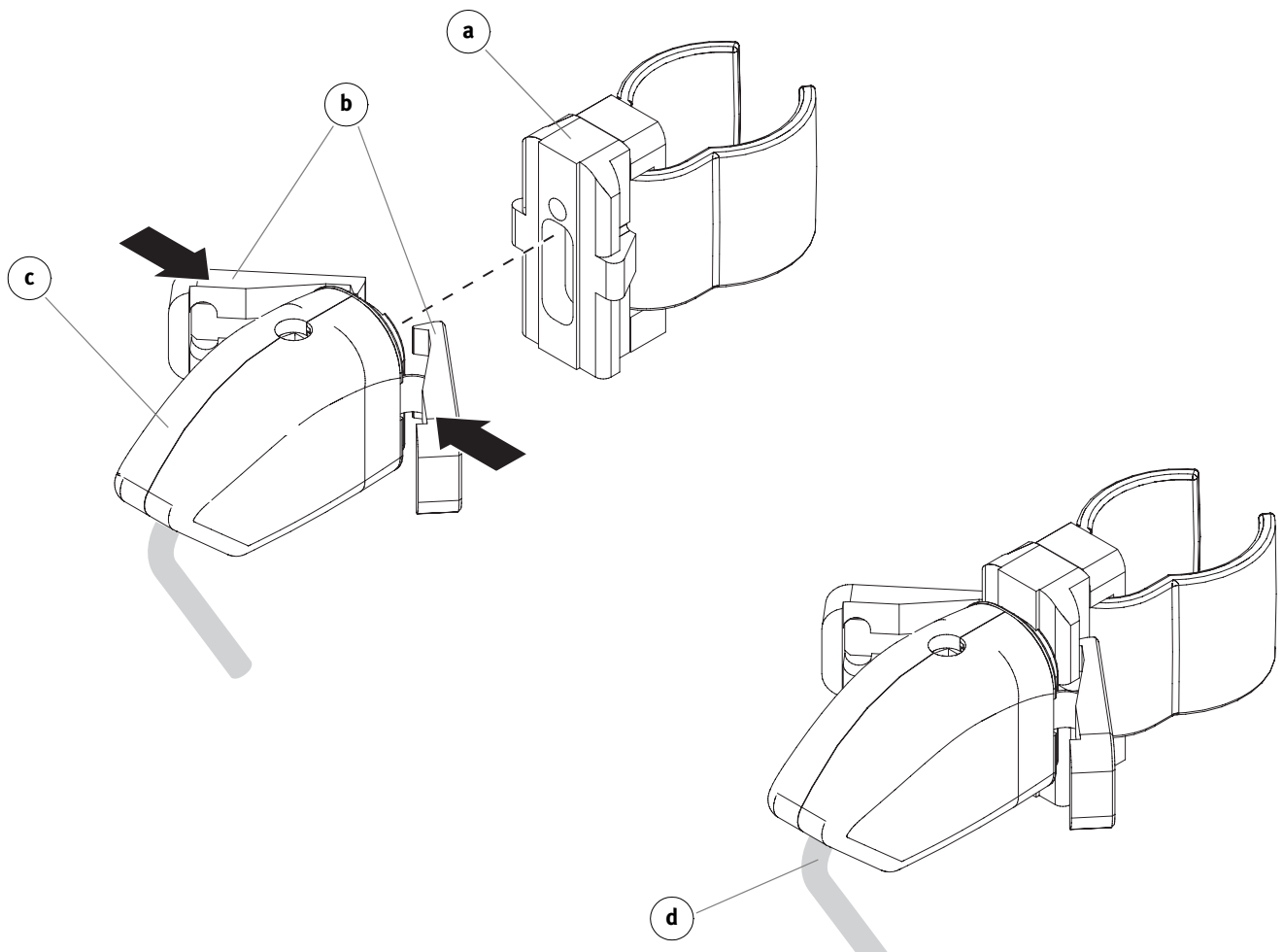


Fig. 4: Mounting the measuring head

- ▶ Position the holder for the measuring head **a** (reference element) on the mast system.
- ▶ Press both fixing clamps **b** together and mount the measuring head **c** onto the holder.
- ▶ Insert the plug of the connection cable **d** into the blue V socket of B-Care₅ sensor module.
You will find detailed information about connections and cable routing for the overall system in the separate operating instructions for the S₅/C₅ System.

Displays after switching the overall system on:

When you switch on the overall system, B-Care₅ runs through a warm-up phase.

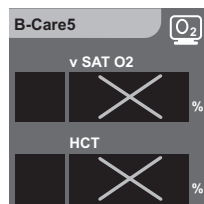
B-Care₅ runs its own separate self-test in addition to the self-test for the overall system. The separate self-test is only performed if the venous sensor is connected to the sensor module.

Option "Function: Off"

→ Display after switching the overall system on

(last selected option "Function: Off"):

During and after the self-test, there is no status display in the B-Care₅ displet.



Display:

Notice that B-Care₅ is not yet switched on.

Option "Function: Off":

If the option "Function: Off" was selected in the menu, the displays of the oxygen saturation, the hematocrit value and the venous temperature are switched off. The key icons for saving or calibration are not displayed.

Note:

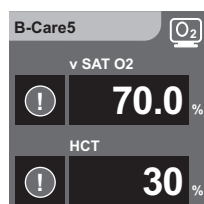
If the option "Function: Off" was selected in the menu and the self-test was successfully completed, switching on the function "Function: On" results in values being shown in the two displays *v SAT O₂* **3** and *HCT* **4**.

Option "Function: On"

→ Display after switching the overall system on

(last selected option "Function: On"):

During the self-test, a sand glass appears in both status displays **5** and **6** in B-Care₅ displet.



→ The self-test is complete.

Indicates that no values have been stored yet for the adjustment.

Taking a blood sample for the laboratory adjustment:

A blood sample must be taken at the start of blood gas monitoring to determine the laboratory values. This sample must be taken immediately before the current values are stored.

- Connect the venous measuring head to the venous connector in the extracorporeal circuit.

To avoid value distortion during the subsequent adjustment with the laboratory values:

- Ensure that the values displayed in the display do not change before you continue.

To carry out the subsequent adjustment using the laboratory values:

B-Care₅

Press the *B-Care₅* menu icon **1** to open the menu.

Function

On

- If necessary, switch the function B-Care₅ back on.

Store current SAT /
HCT for adjustmentNo values
stored

As soon as you have taken the blood sample:

- Press the entry display to save the current values.

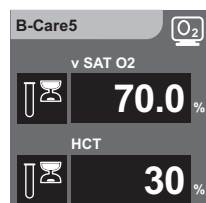
Store current SAT /
HCT for adjustment

Values stored

The current values are stored.



Press the key icon *Return* to return to B-Care₅ display.



→ The status displays **5** and **6** indicate that the laboratory values can be entered.

Note:

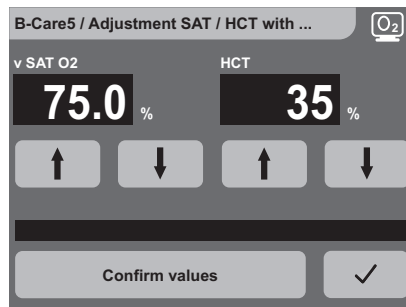
There can be considerable deviation from the reference values of the laboratory device before the laboratory values are entered.

To enter the laboratory values:

Adjustment SAT / HCT
with lab values



Press the entry displet to open the menu for entering the laboratory values:

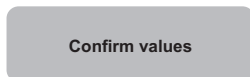


Press the *arrow* icons to enter the laboratory values.



→ Pressing *Up* increases the selected parameter value.

→ Pressing *Down* reduces the selected parameter value.



Press the key icon *Confirm values* to store the laboratory values entered.



Press the key icon *Return* to return to the menu.

When the following displays are shown, no current values can be stored:

Store current SAT /
HCT for adjustment

HI / LO alarm

→ B-Care₅ is in HI alarm or LO alarm.

→ The current values cannot be stored.

- Remove the cause.
- Take a new blood sample.
- Store the current values.

Store current SAT /
HCT for adjustment

Warm-up phase

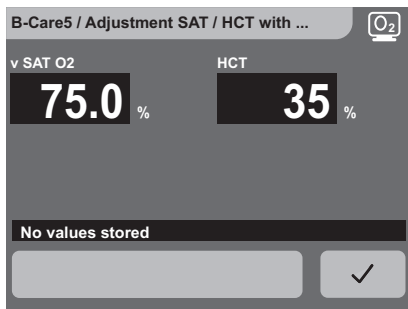
→ The current values cannot be stored during the warm-up phase.

- Wait until the warm-up phase is complete.
- Take a new blood sample.
- Store the current values.

Note:

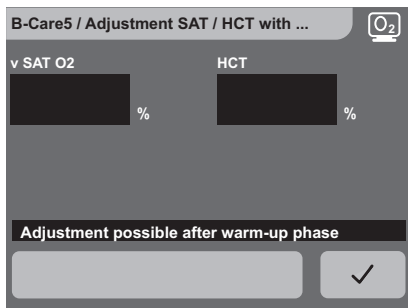
If no *arrow* icons are displayed in the entry displet for laboratory values, an adjustment using the laboratory values is not possible.

If that is the case:



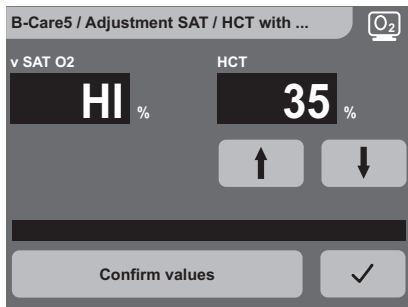
→ No values were stored.

- ▶ Press the key icon *Return* to return to the menu.
- ▶ Take a new blood sample.
- ▶ Store the current SAT / HCT values for the adjustment.



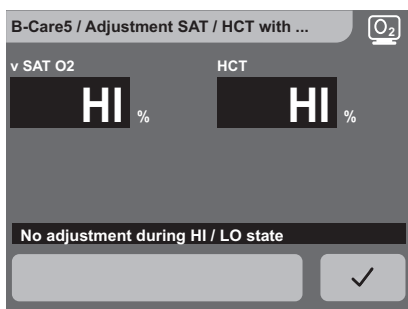
→ Adjustment is not possible during the warm-up phase.

- ▶ Press the key icon *Return* to return to the menu.
- ▶ Wait until the warm-up phase and self-test are complete.
- ▶ Take a new blood sample.
- ▶ Store the current SAT / HCT values for the adjustment.



→ B-Care₅ is in HI alarm (or LO alarm):

- If a HI / LO alarm occurs for one of the two values, adjustment of the second value is possible.



- If a HI / LO alarm occurs for both values, adjustment is not possible.

- ▶ In this case, press the key icon *Return* to return to the menu.
- ▶ Remove the cause of the alarm.
- ▶ Enter the laboratory values.

Other settings:**B-Care₅**

Press the icon for the *B-Care₅ menu 1* to open the menu.
The parameters can be changed as soon as the menu appears.



Press the key icon *Page* to switch between the individual menu pages:

Limits for saturation (SAT)



Press the entry displet to open the sub-menu.

Alarm limit minimum SAT

41

Entering the alarm parameters

Press the corresponding entry displet to enter the lower limit value (input range from 0 to 100%). After the entry is confirmed, the value is displayed in the corresponding entry displet.

Note:

If "0" is entered for the lower limit value, no message appears in the system menu and the alarm tone does not sound in the event of an alarm. Only LO alarm is displayed in B-Care₅ displet.

Warning limit minimum SAT

61

Entering the warning limit values

Press the corresponding entry displet to enter the lower limit value. The value should lie above the selected alarm parameter.

After the entry is confirmed, the value is displayed in the corresponding entry displet.

Warning tone

Off

Switching the warning tone on and off

The warning tone for the saturation warning limits can be deactivated permanently.

Press the entry displet to switch the warning tone on/off. In this example, the warning tone is deactivated.

Note: The alarm tone cannot be deactivated.

Limits for haematocrit (HCT)



Press the entry displet to open the sub-menu.

Alarm limit maximum HCT

50

Alarm limit minimum HCT

20

Entering the alarm parameters

Press the corresponding entry displet to enter the upper or lower limit value (input range from 0 to 100%). After confirming the entry, the values are displayed in the corresponding entry displets.

Note:

If "0" or "100" is entered for the limit values, no message appears in the system menu and the alarm tone does not sound in the event of an alarm. Only LO or HI alarm is displayed in B-Care₅ displet.

Warning limit maximum HCT

45

Warning limit minimum HCT

25

Entering the warning limit values

Press the corresponding entry displet to enter the upper or lower limit value. The limit values should lie within the set interval of the alarm parameters.

After confirming the entries, the values are displayed in the corresponding entry displets.

Warning tone

Off

Switching the warning tone on and off

The warning tone for the warning limits of the haematocrit value can be deactivated permanently.

Press the entry displet to switch the warning tone on/off. In this example, the warning tone is deactivated.

Note: The alarm tone cannot be deactivated.

Name

B-Care₅**Entering a menu name**

If the menu name has not yet been set, press the entry displet.

(After confirming the entry, the name which has been set will appear on the B-Care₅ menu 1 icon).

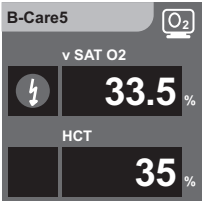
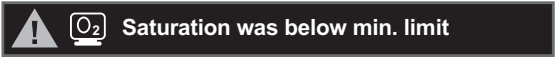


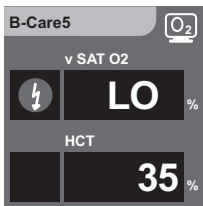
Press the key icon *Return* to confirm entries and/or return to previous menu pages.

1.4.3 Working with B-Care₅ (venous)

When all checks on the overall system (see separate operating instructions) have been successfully carried out and the previously described settings have been implemented, the operator of B-Care₅ is only required to carry out a situation-related adjustment of the measured values for further laboratory measurement values, and respond in an appropriate manner in the event of an alarm or fault.

B-Care₅ (venous): Alarm

Oxygen saturation alarm	Consequences
 – Displet turns red – Display 3 lights up white – Status display 5 Alarm lights up – The alarm tone sounds.	→ The measured value has dropped below the set alarm limit. → There are no other consequences for the operation of the machine.
  ▶ Switch the alarm tone off in the system menu (temporarily). ▶ Take all the steps necessary to stabilize the saturation value above the alarm limit.	→ The measured saturation value dropped below the set alarm limit.
	→ Display in the system menu: Alarm condition has ended and the display can be cleared. → The <i>alarm 5</i> on the status display is cleared automatically. → The alarm is cleared. → The alarm tone is off.

LO oxygen saturation alarm**Consequences**

- Displet turns red
- Display **3** lights up white
- Status display **5 Alarm** lights up

→ LO alarm: The measured value dropped below the measurement range (value below 0%).

- The alarm tone sounds.

→ There are no other consequences for the operation of the machine.

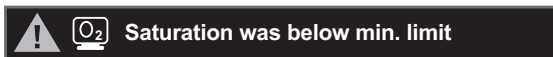


→ The measured saturation value dropped below the measurement range.



- Switch the alarm tone off in the system menu (temporarily).

As soon as the measured value is within the measurement range again:

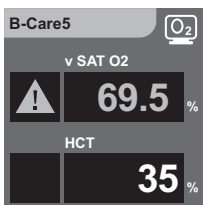


→ Display in the system menu: Alarm condition has ended and the display can be cleared.

→ The *alarm 5* on the status display is automatically cleared.

→ The alarm is cleared.

→ The alarm tone is off.

Warning**Consequences**

- Display **3** lights up yellow
- Status display **5 Warning** lights up

→ The measured value dropped below the set warning limit.

- The warning tone sounds (if activated).

- Take all the steps necessary to stabilize the oxygen saturation value above the limit value.

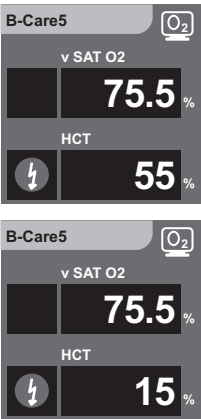
As soon as the measured saturation value is above the set warning limit again:

→ The *Warning* display on the status display **5** is cleared automatically.

→ The warning tone has stopped.

Haematocrit value alarm

Consequences



- Displet turns red
- Display 4 lights up white
- Status display 6 Alarm lights up
- The alarm tone sounds.

→ The measured value exceeded or dropped below the set alarm limits.

 Haematocrit is over max. limit

 Haematocrit is below min. limit

→ Display in the system menu:
The measured haematocrit value exceeded or dropped below the set alarm limits.



- ▶ Switch the alarm tone off in the system menu (temporarily).
- ▶ Take all the steps necessary to stabilize the haematocrit value within the alarm limits.

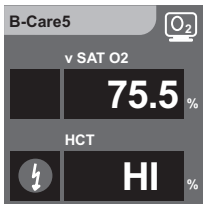
 Haematocrit was over max. limit

 Haematocrit was below min. limit

- Display in the system menu: Alarm condition has ended and the display can be cleared.
- The alarm 6 on the status display is automatically cleared.
- The alarm is cleared.
- The alarm tone is off.

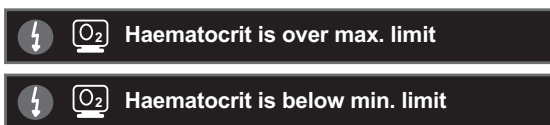
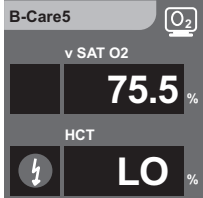
HI / LO haematocrit value alarm

Consequences



- Displet turns red
- Display **4** lights up white
- Status display **6 Alarm** lights up
- The alarm tone sounds.

- HI Alarm: The measured value exceeded the measurement range (value over 100%).
- LO alarm: The measured value dropped below the measurement range (value below 0%).
- There are no other consequences for the operation of the machine.

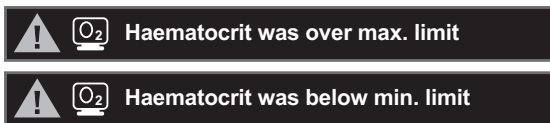


- Display in the system menu:
The measured value is below/above the 0 to 100% measurement range.



- ▶ Switch the alarm tone off in the system menu (temporarily).
- ▶ Clarify and eliminate the cause (e.g. adjustment of the sensor position).

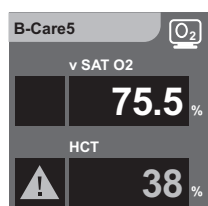
As soon as the measured value is within the measurement range again:



- Display in the system menu: Alarm condition has ended and the display can be cleared.
- The *alarm 6* on the status display is automatically cleared.
- The alarm is cleared.
- The alarm tone is off.

Warning

Consequences



- Display **4** lights up yellow
- Status display **6** *Warning* lights up

→ The measured value is above/below the set warning limits.

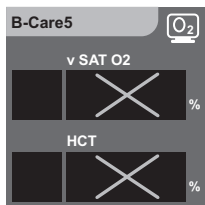
- The warning tone sounds (if activated).

- Take all the steps necessary to stabilize the haematocrit value inside the limit values.

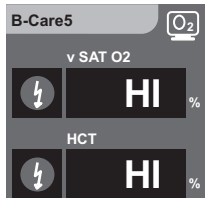
As soon as the measured haematocrit value is within the set warning limits again:

- The *Warning* display on the status display **6** is cleared automatically.
- The warning tone has stopped.

Other displays on the displet

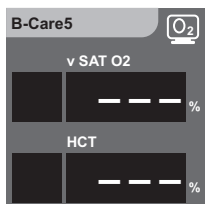


B-Care₅ is switched off (the option "Function: Off" was selected from the menu)

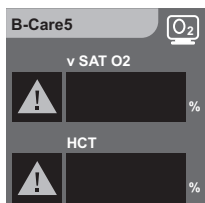


Display when a deviation from the measurement range limits occurs

- HI Alarm
- The alarm tone sounds.
- Display in the system menu: "Sensor is not mounted"



Display when a sensor is not connected or is defective



Display if a sensor module is defective.

Other displays

Faults and disruptions appear directly as a text message in the system menu.

Display in the system menu:

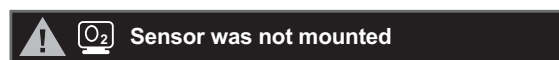
Possible causes

→ Consequences



The measuring head is not correctly connected to the holder or to the venous connection.

- ▶ Mount the measuring head correctly.



- Display in the system menu: The display can be cleared.
- The *Alarm* display on the status displays **5** and **6** is cleared automatically.
- The HI alarm display on the displet is cleared automatically.
- ▶ Clear the message.

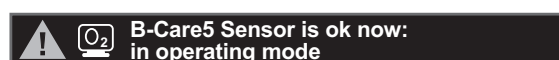


The self-test failed because the measuring head was not mounted correctly on the holder or because of contamination on the measuring head.

- ▶ Tighten the measuring head on the holder or remount it correctly.
- ▶ Clean the measuring head.
- ▶ Mount the measuring head again if required.

The self-test is repeated.

- The *sand glass* in the status displays **5** and **6** is displayed until the self-test is completed successfully. As soon as the self-test has been completed successfully, the message is overwritten:



- Display in the system menu: The display can be cleared.
- B-Care₅ can be used again.
- ▶ Clear the message.



The sensor is defective.

- ▶ Complete the perfusion without B-Care₅.
- ▶ When the perfusion has ended, the sensor should be given to an authorized service technician without delay.



B-Care₅
Module defective



B-Care₅
Module was defective

The module has an internal defect.

- Display in the system menu: The display can be cleared.
- B-Care₅ can be used again.

If the "Module defective" message is not replaced with "Module was defective" within a short space of time, the module is defective. In this case, proceed as follows:

- ▶ Complete the perfusion without B-Care₅.
- ▶ When the perfusion has ended, the module should be given to an authorized service technician without delay.



B-Care₅: Display module firmware not compatible

B-Care₅ cannot be operated with the current firmware version of the display and control modules.

You will find details of this inside the front cover and in the separate operating instructions for the S₅/C₅ System.

- The firmware version must be updated by your authorized service technician.



B-Care₅: incompatible hardware of display module

B-Care₅ cannot be operated with the current hardware version of the display and control modules.

- Contact your service technician.

Special function

The sensor module and the measuring head normally constitute a unit and they should not be operated separately. The measuring head values are stored in the sensor module.

Warning:
You should only alter the measuring head parameters if the measuring head has to be replaced. Do not alter the measuring head parameters for training purposes.
Enter the measuring head parameters with great care. Incorrect entries result in incorrect measured values.



Adjust parameters
venous sensor

Press the entry displet to open the sub-menu.

Press the key icon *Page* to switch between the individual menu pages:

Serial number of the sensor

1875

C1

54.6

Entering the measuring head parameters
Press the corresponding entry displets to enter the measuring head parameters. The relevant information can be found on the label on the housing of the measuring head.

to

C9

1

After confirming the entries, the values are displayed in the corresponding entry displets and in the measuring head display displet.

Display parameters
venous sensor

Press the relevant entry displet to check the entered values.

B-Care5 / Display parameters venous sensor

Serial number of the sensor 1875

C1 54.6 C6 110

C2 145.2 C7 0.700

C3 0.035 C8 48

C4 127 C9 1

C5 0.029

Press the *Return* key icon to close the display.

After entering the measuring head parameters:

- ▶ Tighten the measuring head on the holder.
- ▶ Press the entry displet *Self-test with reference element* to start the self-test.

Self-test with
reference element

Self-test
running

The self-test is performed.

Self-test with
reference element

Self-test ok

As soon as the self-test has been completed successfully:

→ Self-test completed successfully.

If the self-test failed:

Self-test with
reference element

Self-test
failed

Self-test not completed successfully:

- ▶ Eliminate all possible causes of fault (e.g. the measuring head is not secured correctly to the holder).
- ▶ Press the entry displet *Self-test with reference element* to restart the self-test.

If the self-test fails again, there is a defect in the system.

- ▶ Arrange to have a service technician inspect the sensor module and the venous sensor.

Displays in the system when new parameter values are set:



All set values entered for the measuring head must be checked for plausibility. The entered values must correspond to the information (serial number, C₁ to C₉ data) on the label on the housing of the measuring head.

- ▶ Compare the entered values for the measuring head with the information on the label.
- ▶ If incorrect values were entered, they should be corrected.
- ▶ Clear the message in the system menu.

If the message is displayed again, there is a defect in the system.

- ▶ Complete the perfusion without B-Care₅.
- ▶ Contact your service technician.

1.5 Appendix

1.5.1 Electrical specifications

B-Care₅	
Measurement range SAT/HCT	0 to 100%
Measurement range temperature	0 to 50 °C
Measuring interval	1 second
SAT resolution	0.1%
HCT resolution	1%
Temperature display resolution	0.1 °C
Accuracy of oxygen saturation measurement	in the 60 to 100% range: ±3% in the 40 to 59% range: ±5%
Accuracy of haematocrit value measurement	in the 15 to 50% range: ±5%
Accuracy of temperature measurement	in the 25 to 40 °C range: ±0.5 °C (at room temperature of 23.5 °C)

You will find more information on the technical specifications in the operating instructions for the S₅/C₅ System.

1.5.2 Labeling and inscription

Icons on the sensor modules:

V	Channel for connection to venous sensor (color-coded blue)
	S ₅ /C ₅ sensor module for B-Care ₅

You will find more information about labelling in the operating instructions for the S₅/C₅ System.

Inscription on label:

Ser. No.	Serial number of the venous sensor
C1 ... C9	Parameters of the venous sensor

1.5.3 Part numbers

B-Care ₅ for the S ₅ /C ₅ System			25-60-00
consisting of:			
	B-Care ₅ sensor module (venous)		25-60-20
	Venous sensor (complete)		97-231-059
	Holder for measuring head (reference element)		25-60-30
Accessories			
	SORIN GROUP 1/2" venous measuring connector	50 units (sterile)	05171
	SORIN GROUP 3/8" venous measuring connector	50 units (sterile)	05172
Spare parts set (complete)			60303
consisting of:			
	Venous sensor		
	CD with sensor parameters		
	Waterproof pen		

Information on accessories and part numbers can be found in the operating instructions for the S₅/C₅ System.

1.5.4 Warranty

The contractually agreed guarantee conditions apply here.

